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(54) TEST STRIP HOLDER AND METHOD OF USE

TESTSTREIFENHALTER UND VERFAHREN ZU DESSEN VERWENDUNG

PORTE-BANDELETTE D'ESSAI ET SON PROCEDE D'UTILISATION

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Description

BACKGROUND

[0001] This invention relates to a holder for a test strip and a method of using the holder. The test strip holder positions a test strip within a liquid to ensure that liquid contacts and moves up the test strip only by capillary action.

[0002] Conventional test strips are hand-held and immersed in the liquid. The test strip is then removed from the liquid and the results are determined from reading the test strip. In this "immersion" method, the tester is required to physically hold the test strip in the liquid. This can result in problems arising from contamination of the test strip from the tester's fingers, which may result in unreliable or tainted results.

[0003] Further problems may arise from prolonged contact of the test strip with the liquid to be tested. Some test strips require contact with a liquid for a predetermined time period. If the strip contacts the liquid for an extended period of time, the results may be faulty or unreliable.

[0004] Other known test strips require application of a specific volume to the test strip, for example a predetermined number of drops. Other test strips require immersion of the test strip in a liquid up to a prescribed height for a designated period of time. These types of test strips require extensive and exacting tester interface. The tester must maintain constant surveillance of the test strip and liquid to ensure proper test conditions. This is an inefficient use of the tester's time. Further, it can easily lead to errors in the testing.

[0005] Holders for test strips are known that include a test strip enclosed within a housing. However, this type of test strip holder also suffers from the above disadvantages, such as the need for continuous monitoring and careful measuring. The housing must be dipped into a liquid to a certain height for a predetermined time. The tester must hold the holder or cause the holder to be supported at the predetermined depth for the designated time period. If the test strip and housing are inserted beyond the depth and/or for more or less than the predetermined time, the results from the test may be inaccurate and unreliable.

[0006] Further, known test strip holder devices do not include any structure to assure that the liquid contacts the test strip only up to a certain predetermined height. Even if the housing is provided with a mark designating the insertion depth, the tester must manually hold the test strip holder in the liquid for a designated period of time. Further, depending on the clarity of the liquid and the container in which the liquid is held, it is difficult to accurately position the test strip holder with the mark positioned at the surface of the liquid.

[0007] Known test strip holders also do not ensure the positioning of the test strip away from the internal side walls of the holder. Therefore, the liquid may travel up the side walls of the test strip holder by capillary action and prematurely contact the test strip, rather than only travel up the test strip. Premature contact of the test strip with liquid may cause faulty and unreliable test results, especially if the test strip is provided with a plurality of test strip zones that are to be sequentially contacted. Moreover, direct and prolonged liquid contact with the strip may cause unreliable test results.

[0008] U.S. Patent No. 4,999,285 to Stiso is directed to a chromatographic device. The device comprises, in combination, a housing and a strip of bibulous material non-removably confined in the housing. The strip has a length and width only slightly less than the length and width of the inner walls of the housing. The inner walls of the housing have means attached thereto for supportively confining the strip in the housing. The strip is confined so that (1) the front and back of the strip are essentially free from contact with the walls of the housing and (2) the capillary action of the strip remains substantially unchanged, and (3), where the strip is paper, the strip is allowed to expand as it is traversed by the liquid medium. The bottom end of the housing contains means for enabling contact of a portion of the strip with the liquid medium. The housing further contains means for visually observing the strip and can also contain indicating means cooperative therewith to assist in determining the result of a chromatographic test.

[0009] WO 94/02850 is directed to a test device for detecting or measuring analytes in a test sample, which comprises a transparent, impervious, rigid and hollow housing containing an assay test material. The device is constructed such that light can pass through both the housing and assay material. Various assays can be conducted using the device, resulting in an optical change or changes usually based upon the amount of analyte in the test sample, which change is detected visually or by an optical instrument.

[0010] U.S. Patent No. 5,135,873 to Patel et al. is directed to methods and devices for permitting capillary flow of liquid between two or more pieces of bibulous material which, prior to actuation, are in a non-capillary flow relationship. In particular, the device is actuated and capillary flow relationship is initiated between the two or more pieces of bibulous material in non-capillary flow relationship by utilizing a liquid expandable piece of bibulous material.

[0011] U.S. Patent No. 5,384,264 to Chen et al. is directed to a method and apparatus for performing assays in a single step, which does not require the user to perform a washing step, does not require the user to add any reagent or other solution other than analyte sample fluid to the apparatus, and does not require the user to come into contact with the apparatus at any point during the assay procedure after the fluid suspected of containing a particular ligand is added to the apparatus. The apparatus for performing the assay consists of a single container with at least three ports disposed through different planes in the body of the apparatus beneath

which labelled antiligand (the first port), unlabelled antiligand (the second port), and unlabelled ligand (the third port) are disposed. Said labelled antiligand is complementary to both the analyte of interest and the unlabelled ligand, the latter of which serves as a control display for comparison of any color changes mediated by the label visible through the second port. The antiligands and ligands disposed beneath each port are bound to separate membranes. At least the first membrane is bibulous and is disposed at one end of a ramp where, at the top of which, it overlaps the second membrane thus slowing the flow of sample and improving the performance of the assay.

[0012] U.S. Patent No. 5,500,375 to Lee-Own et al. is directed to integrated package-holder assay devices for detecting the presence of analyte in a sample. The device serves the dual roles of supporting and protecting an immunochromatographic assay. The device is compatible with any immunochromatographic assay format. The assay can be performed in a single apparatus for use in a laboratory or a field setting. In a specific example, the assay device is a nylon membrane formatted for an immunochromatographic assay sealed between transparent adhesive tape and a stiff plastic strip. White tape placed over the plastic strip defines a window for observing the assay results.

[0013] EP 0 560 411 is directed to an analytical test device comprising a hollow casing constructed of moisture-impervious solid material, such as plastic materials, containing a dry porous carrier which communicates indirectly with the exterior of the casing via a bibulous sample receiving member which protrudes from the casing such that a liquid test sample can be applied to the receiving member and permeate therefrom to the porous carrier. The carrier contains, in a first zone, a labelled specific binding reagent that is freely mobile within the porous carrier when in the moist state, and in a second zone, spatially distinct from the first zone, unlabelled specific binding reagent for the same analyte, which unlabelled reagent is permanently immobilized on the carrier material and is therefore not mobile in the moist state. The two zones are arranged such that liquid sample applied to the porous carrier can permeate via the first zone into the second zone. The device incorporates means, such as an aperture in the casing, enabling the extent, if any, to which the labelled reagent becomes bound in the second zone to be observed.

[0014] U.S. Patent No. 5,356,782 to Moorman et al. is directed to an apparatus useful in carrying out an analytical assay. The apparatus has a positive and negative control, as well as a site for determining the presence, amount, or lack of an analyte in a sample. The apparatus comprises an absorptive material and a plurality of zones in the direction of fluid flow. A first negative control zone of said absorptive material contains an immobilized reactant which does not bind to said analyte of interest. A second analytic control zone of said absorptive material contains an immobilized reactant which specifically binds to said analyte of interest. A third positive control zone of said absorptive material contains both an immobilized reactant which specifically binds to said analyte of interest, and a portion of the analyte of interest in solubilizable form, wherein said portion of the analyte is solubilized when contacted with the liquid sample and reacts with the immobilized reactant of said third zone.

SUMMARY OF THE INVENTION

[0015] The invention provides a reliable test strip holder and method of use of the test strip holder. The test strip holder can be inserted into any depth in a liquid to be tested and left in the liquid with testing zones of the test strip out of direct contact with the liquid. The tester is not required to continuously monitor the insertion depth of the test strip. The test strip holder maintains the test strip spaced from the sides of the test strip holder, wherein the liquid flows up the test strip by capillary action within the strip only. The test strip is not wetted by liquid on the inner walls of the elongated hollow member. This avoids premature contact of the test strip with the liquid and unreliable testing results.

[0016] The invention provides a test strip holder and method of use that overcomes the problems associated with known test strip holders and methods especially that of US Patent 4 999 285 which represents the closest prior art. The test strip holder accurately positions a test strip in a liquid so liquid travels up the test strip only by capillary action of the strip and liquid.

[0017] The invention provides a test strip holder or holding apparatus having the features of claim 1 and a method of use having the features of claim 17.

[0018] When the test strip holder is inserted into a liquid, the liquid rises inside the elongated hollow member only to the level of the at least one vent. Air or other ambient atmosphere in the interior of the elongated hollow member can initially exit through the at least one vent as the liquid enters. Once the liquid covers the at least one vent, the pressure of the air or ambient atmosphere in the elongated hollow member above the at least one vent prevents the liquid from further entering the elongated hollow member. Thus, the test strip is in contact with the liquid only in a predetermined designated area, designed for direct contact with the liquid. The position of the vent on the sidewall of the elongated hollow member determines the maximum height that the liquid can actually enter the elongated hollow member. The actual test strip test zones are preferably not in direct contact with the liquid and are wetted only by capillary action of the liquid on the test strip.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] Embodiments of the invention will be described in detail with reference to the following drawings in which like reference numerals refer to like elements

and wherein:

Fig. 1 is a sectional view of a test strip holder according to a first embodiment of the invention;
Fig. 1A is a sectional view of a test strip holder with a self sealed closed end according to a first embodiment of the invention;
Fig. 2 is a cross-sectional view along line II-II of Figure 1;
Figs. 3A-3C illustrate the insertion of the test strip holder of Fig. 1 into a liquid to be tested;
Fig. 4 is a front view of the test strip holder in the open condition according to a second embodiment of the invention;
Fig. 5 is a part sectional view of the test strip holder of Fig. 4;
Fig. 6 is a front view of the test strip holder in a closed condition of Fig. 4;
Fig. 7 is a cut away top sectional view of the test strips holder of Fig. 4;
Figs. 8A-8C illustrate the insertion of the test strip holder of Fig. 4 into a liquid;
Fig. 9 is a front view of the test strip holder in the open condition according to a third embodiment of the invention; and
Fig. 10 is a front view of the test strip holder in a closed condition of Fig. 9.

DESCRIPTION OF PREFERRED EMBODIMENTS

[0020] The elongated hollow member of the holder may be formed with a rounded cross-section, for example, as a tubular conduit. Alternatively, the elongated hollow member may be formed as two separate mateable parts, which are sealed around their periphery. The elongated hollow member may be formed in other configurations, as long as the elongated hollow member defines an open end and a sealed closed end with at least one vent positioned between the open and closed ends. The position of the at least one vent in the elongated hollow member can be varied to vary the depth of immersion of the test strip.

[0021] The elongated hollow member also defines support structure for the test strip, which maintains the test strip spaced from the walls of the elongated hollow member. The support structure may be an element separate from the elongated hollow member and inserted into the elongated hollow member. Alternatively, the support structure may be formed integrally with the elongated hollow member.

[0022] The support structure may take any form appropriate complementary to the test strip holder, as long as the test strip is maintained spaced from the walls of the elongated hollow member. This prevents the test strip zones from being contacted by any liquid on the sidewalls of the elongated hollow member. Liquid normally flows by capillary action in a path of "least resistance." Contact between the test strip and the sidewalls of the test strip holder creates a low resistance capillary channel and provides a "short circuit" for the liquid up the edges of the test strip, thereby bypassing a front surface of the test strip. This can lead to erroneous and unreliable results.

[0023] The spacing of the test strip from the side walls of the elongated hollow member ensures that liquid, under normal atmospheric conditions, flows up the test strip by capillary action when the test strip holder is inserted open end down into a liquid. Liquid does not contact the test strip from the side walls of the test strip holder based on the configuration of the test strip holder. The size of the test strip holder and the configuration of the open end may vary depending on characteristics of the liquid to be tested, but can be readily determined by routine experimentation.

[0024] The closed end of the elongated hollow member is sealed so that air cannot exit. The absence of air exiting prevents liquid from moving up the elongated hollow member beyond the at least one vent other than by capillary action within the test strip. The position of the at least one vent in the elongated hollow member can be predetermined to select the depth of immersion of the test strip.

[0025] The test strip can take any appropriate form and can include at least two separate and distinct testing zones. These testing zones are designed to bind moving liquid reagents to the test strip in proportion to the concentration of the substance tested for in the liquid. The testing zones can measure for different substances within the liquid, thereby avoiding multiple tests and potential contamination of the liquid by different test strips and/or test strip holders. Therefore, it is important that the test strip be wetted by the capillary action of the liquid. Direct contact of liquid with the testing zones can alter the results or cause the test to be unreliable.

[0026] Further, the test strip may include a sample pad, conjugate pad, a membrane, which includes the testing zones used in the actual testing, and a wicking pad. A piece of opaque (e.g., white) waterproof tape may be applied over the sample and conjugate pads and a part of the membrane. The tape masks the strip during development and also eliminates confusion regarding the location of the zones during testing. The tape applies pressure to the sample pad to facilitate the liquid's flow on the test strip. Further, the tape protects the test strip during manufacturing and particularly during insertion into the test strip holder.

[0027] Fig. 1 illustrates a first embodiment of the test strip holder 1. The test strip holder 1 includes an elongated hollow member 2. Elongated hollow member 2 is preferably constructed from a clear transparent material. The elongated member 2 may be perfectly clear or opaque in all regions, except where testing zones of the test strip 9 (discussed hereinafter) are located. In that region, the elongated hollow member is preferably transparent to permit the test strip to be viewed. The elongated hollow member 2 may also be provided with

indicia, such as graduations, markings or the like, for identifying the testing zones. The elongated hollow member 2 may be made from any suitable non-reactive material, such as plastic, glass, or other such materials.

[0028] The elongated hollow member 2 has a circular cross-section, as seen in Fig. 2. However, any appropriate configuration of the elongated hollow member may be possible. The elongated hollow member 2 includes an open end 3 and an end 4 closed in an air-tight fashion.

[0029] The closed end 4 of the elongated hollow member may be formed in any suitable manner, as long as an airtight sealed end is formed. As seen in Fig. 1A, the closed end 4A may be formed by forming a sealed end from the elongated hollow member itself. Thus, the closed end 4A is sealed airtight to prevent the escape of air from the closed end 4A, without the need for additional components.

[0030] Alternatively, the closed end 4 may be sealed by an airtight sealing plug 5 inserted into the elongated hollow member 2 as in Fig. 1. Air tight sealing plug 5 prohibits air from entering or exiting the elongated hollow member 2 at the closed end 4. The airtight sealing plug 5 may rely on resilient characteristics to form the seal. Moreover, an adhesive (not shown) may be placed between the airtight plug 5 and the elongated hollow member 2 at the closed end 4 to enhance the seal at the closed end 4. Further, the seal at the closed end 4 may be enhanced by covering the plug 5 with suitable covering (not shown), including epoxy, wax, adhesive, or the like, or a further sealing cap.

[0031] The open end 3 of the elongated hollow member 2 includes an open plug 6, which may be made of rubber or other material. The open plug 6 is preferably fit within the open end of the elongated hollow member 2. The open plug 6 includes a through passage 7 colinear with a longitudinal axis 8 of the elongated hollow member 2. The through passage 7 permits liquid to pass up through the open end 3 of the elongated hollow member 2 when the elongated hollow member 2 is inserted into a liquid, as described hereinafter.

[0032] The test strip 9 has a length substantially equivalent to the overall length of the elongated hollow member 2. The width of the test strip 9 is less than the inner diameter of the elongated hollow member 2. The width of the test strip 9 is substantially equal to the diameter of the through passage 7. Therefore, as seen in Fig. 1, when the test strip 9 is positioned within the elongated hollow member 2 and the through hole 7 of the open plug 6, the test strip 9 is held in the test strip holder 1 by a friction fit of the test strip 9 in the through passage 7. Further, the friction fit holds the test strip 9 spaced from the inner walls of the elongated hollow member 2.

[0033] The elongated hollow member 2 includes at least one vent or opening 10. The vents 10 may be circular, elliptical or any other appropriate shape. As seen in Fig. 1, there may be two or more vents 10. The vents 10 are preferably located proximate the open end 3 of the test strip holder 1. However the positioning of the vents 10 may be anywhere intermediate the open end 3 and closed end 4 of the elongated hollow member 2. As the vents 10 define the extent of liquid entry into the elongated hollow member 2 (as described hereinafter), it is preferable that the vents be located proximate the open end 3. Further, it is desirable to only physically and directly wet a designated area of the test strip 9, the vents should be positioned on the elongated hollow member 2 at a level approximately corresponding to the maximum level of direct physical wetting for the test strip 9.

[0034] The operation of the test strip holder will now be discussed, with reference to Figures 3A-3C. Initially, the test strip holder 1 is inserted into a container C holding the liquid L to be tested. Upon initial contact of the test strip holder 1 with the liquid L, the liquid L enters the open end 3 of the elongated hollow member 2 through the through passage 7 in the open rubber plug 6. Air within the elongated hollow member 2 is displaced up and exits the interior of the elongated hollow member 2 through the vents 10, as indicated by vent path A.

[0035] Upon further insertion of the test strip holder 1 into the liquid L, the liquid L rises within the elongated hollow member 2, as in Fig. 3B. When the elongated hollow member 2 is immersed in the liquid L up to and covering the vents 10, as in Fig. 3C, the vent path A is closed as it is covered with liquid L. Therefore, the pressure within the elongated hollow member 2 above the liquid L increases. Liquid is prevented from further entering the elongated hollow member 2. The position of the vent 10 on the sidewall of the elongated hollow member 2 determines the maximum height that the liquid can actually enter the elongated hollow member 2.

[0036] The test strip 9 is positioned within the through passage 7 of the open rubber plug 6, thus spacing the test strip 9 from the walls of the elongated hollow member 2. Due to the spacing of the test strip 9 from the walls of the elongated hollow member 2, the capillary action of the liquid L contacting the test strip 9 is the only way that the liquid L contacts the testing zones Z1, Z2. The liquid L contacts only a bottom portion of the test strip 9 up to the level L1 defined by the vents 10 and does not directly contact the testing zones Z1 and Z2. Thus, erroneous and unreliable results, caused by direct contact of the liquid L and the zones Z1, Z2 of the test strip 9, are avoided.

[0037] A second embodiment of the test strip holder 1', is shown in Figures 4-8C. Here, an elongated hollow member 20 is formed by a test strip receiving part 21, which positions the test strip, and a test strip covering part 22. The test strip receiving part 21 and the test strip covering part 22 are connected at hinge 23. The parts 21, 22 are hinged together so the test strip covering part 22 closes onto the strip receiving part 21 to define the elongated hollow member 20. While the hinge 23 is shown parallel to a longitudinal axis of the parts 21, 22, the hinge could be provided parallel to an axis trans-

verse to the parts 21, 22.

[0038] In the embodiments of Figs. 4-8C, the test strip receiving part 21 includes a peripheral groove or channel 24, which is spaced from a test strip receiving channel 26. The test strip covering part 22 includes a peripheral protrusion 25 that is formed in a shape and size complementary to the peripheral groove or channel 24. When the test strip covering part 22 is pivoted about the hinge 23 and closed on the test strip receiving part 21, the peripheral protrusion 25 enters into and forms a seal with the peripheral groove or channel 24. The shape of the peripheral groove or channel 24 and the extending peripheral protrusion 25 mate so an airtight seal is formed around the elongated hollow member 20. The peripheral groove or channel 24 and peripheral extending protrusion 25 can mate in a "snapping" fashion to define the seal.

[0039] Further, an adhesive sealant (not shown) may be positioned within the groove or channel 24 prior to closing the test strip covering part 22 to enhance the airtight seal. Alternatively, a pressure sensitive adhesive (not shown) may be positioned within the peripheral groove or channel 24 or on the peripheral protrusion 25 so when the test strip covering part 22 is closed, the pressure sensitive adhesive is activated and the airtight sealing relation is enhanced.

[0040] Also, the test strip covering part 22 and the test strip receiving part 21 may be sealed by ultrasonic welding, rf (radio frequency) welding, plasma welding or the like. The welding may occur at the protrusion 25 and groove 24. Alternatively, the elongated hollow member 20 may be sealed by welding, not at the groove 24 or protrusion 25.

[0041] The peripheral groove or channel 24 and the peripheral protrusion 25 may be constructed in any shape and form, so long as the mating of the test strip receiving part 21 and test strip covering part 22 can form a sealed elongated hollow member 20.

[0042] The test strip receiving part 21 is shown in Figs. 4-7 with the peripheral groove or channel 24 and the test strip covering part 22 having the peripheral protrusion 25. Alternatively, the test strip receiving part 21 may be provided with the protrusion 25 and the test strip covering part 22 may be provided with the peripheral groove on channel 24.

[0043] The test strip channel 26 in the test strip receiving part 21 preferably includes at least two notched test strip holders 27. The notched test strip holders 27 may be integral with the elongated holder member 20 or be a separately attached element. The notched test strip holders 27 include two raised side portions 27a surrounding a planar center support surface 27b. The test strip 9 is positioned on the planar center support surface 27b. Movement of the test strip 9 is constrained by the raised side portions 27a. As seen in Fig. 5, there are two notched test strip holders 27 to position the remote ends of the test strip 9 spaced from the walls of the elongated hollow member 20. While the figures show two notched strip holders, any number of notched strip holders may be used, as long as the test strip 9 is maintained spaced from the sidewalls.

[0044] A test strip stop 28 is positioned proximate the open end 29 of the elongated hollow member 20. The test strip stop 28 maintains the test strip 9 within the test strip channel 26, especially when the test strip holder 1' is vertical. The test strip stop 28 prevents the test strip 9 from slipping out of the test strip channel 26 and assists in permitting the bottom of the test strip 9 to be in contact with the liquid L.

[0045] A bottom support 30 can be provided within the test strip channel 26 for further supporting the test strip 9 from the inner walls of the elongated hollow member 20. While the figures show one bottom support 30, any number of bottom supports may be provided in the test strip channel 26.

[0046] The test strip covering part 22 includes a window or vent 42. The vent 42 is shown as an elongated rectangle having substantially the same width as the test strip channel 26. However, the vent 42 may take any appropriate size and shape as long as the air can be vented from the test strip channel 26. The vent 42 functions substantially similar to the vents 10 of the first embodiment.

[0047] A test strip 9 shown in Fig. 5, can be used with either embodiment. The test strip 9 includes at least two separate and distinct test strip zones Z1, Z2 at membrane 33. These zones Z1, Z2 can bind the moving liquid reagents to the test strip 9 in proportion to the concentration of the substance tested for in the liquid L. The zones Z1, Z2 can measure for different substances within the liquid, therefore, it is important that the test strip be appropriately contacted by the capillary action of the liquid L. Direct contact of liquid L with the zones Z1, Z2 can alter the results or cause the test to be ruined.

[0048] Further, the test strip may include a sample pad 34, and conjugate pad under the sample pad and a wicking pad 35 contacting the membrane 33. A piece of white opaque waterproof tape (not shown) may be applied over the sample pad 34 and a part of the membrane 33. The opaque waterproof tape masks the test strip 9 during development. The tape also eliminates confusion regarding the location of the zones Z1, Z2 during testing. The tape applies pressure to the sample pad 34 and to the underlying conjugate pad to facilitate the liquid's flow up the test strip 9. The tape protects the test strip 9 during manufacturing and during insertion of the test strip 9 into the test strip holder 1,1' or 1".

[0049] Test strip zones Z1, Z2 determine the presence of certain substances. The number of test strip zones is not limited to two, and any number of test strip zones Z1, Z2 may be provided. Further, any test strip 9 may be used with the test strip holders 1,1' or 1". The type of test strip 9 may be changed, as needed, for the specified compound that the test is designed to discover.

[0050] Suitable test strips 9 include strips of material impregnated with compounds, which react with other

compounds, normally in a liquid. The reaction may , for example, cause a change in color of the impregnated strip, where the change in color is representative of the concentration of the compounds in the liquid. Examples of such strips are pH strips; pregnancy test strips; immunoassay test strips; antigen, antibody and polynucleotide test strips; and test strips of analytes, such as drugs, metabolites, pesticides, pollutants and the like. The above types of test strips are only examples and any other suitable test strip may be used in the test strip holder 1, 1' or 1". A detailed discussion of examples of suitable test strips appears in U.S. Patent No. 4,857,453. U.S. Patent No. 4,857,453 to Ullman et al. is directed to a device for conducting an assay method. The device comprises a housing, means enclosed in the housing for capturing a member of a specific binding pair in a zone and for allowing liquid to be transported by capillary action away from the zone, one or more self-contained liquid reagents enclosed in the housing for conducting an assay method for the determination of an analyte in the sample, and means in the housing for introducing the sample into the device. Preferably, the self-contained reagents are liquid reagents which are contained in a breakable container. The device of the invention finds use in assay methods for the determination of an analyte in a sample suspected of containing the analyte.

[0051] Figures 8A-8C show the immersion of the test strip holder 1' into a liquid L in a container C. Upon initial contact of the test strip holder 1' with the liquid L, the liquid L enters the open end 29 of the elongated hollow member 20. The air within the elongated hollow member 20 is displaced through the vent 42, as indicated by vent path B. Upon further insertion of the test strip holder 1' into the liquid L, the liquid L rises within the elongated hollow member 20. When the elongated hollow member 20 is immersed in the liquid L up to level L1 and covering the vent 42, the vent path B is no longer open to air. Therefore, the pressure within the remainder portion of the elongated hollow member 20 increases. Liquid L is thereby prevented from further entering the elongated hollow member 20.

[0052] The test strip 9 is in contact with the liquid L only in a predetermined designated area, designed for direct contact with the liquid. The position of the vent 42 on the sidewall of the elongated hollow member 20 determines the maximum height that the liquid L can actually enter the elongated hollow member 20. The actual test strip test zones Z1,Z2 are preferably not in direct contact with the liquid L and are wetted only by capillary action of the liquid on the test strip 9.

[0053] The test strip 9 is positioned within the test strip channel 26 and is spaced from the walls of the elongated hollow member 20 by the notched test strip holders 27 and the bottom support 30. The capillary action of the liquid L contacting the test strip 9 permits the liquid to contact the testing zones Z1,Z2 of the test strip 9. The liquid L directly contacts only a bottom portion of the test strip 9, because the vent 42 limits the extent of liquid L able to enter the elongated hollow member 20. Liquid L does not directly wet the testing zones Z1,Z2. Thus, erroneous and unreliable test results caused by direct wetting of the zones Z1,Z2 by the liquid L are avoided.

[0054] While the vent 10 or 42 is shown as at least one hole in the elongated hollow member 2 or 20, the vent 10 or 42 could be defined by a mesh (not shown). The mesh may cover one or all of the vents 10 or 42. Alternatively, the mesh may constitute the entire bottom portion of the elongated hollow member 2 or 20 where the top edge of the mesh defines the extent that the liquid L enters the elongated hollow member 2 or 20.

[0055] Figures 9 and 10 illustrate a third embodiment of the test strip holder. The test strip holder 1" is similar in construction to the second embodiment and similar elements are designated with similar, but primed, reference characters.

[0056] The test strip holder 1" includes an elongated hollow member 20", which is formed from a test strip receiving part 21", which positions the test strip, and a test strip covering part 22". Unlike the second embodiment, the test strip receiving part 21" and the test strip covering part 22" are not hingedly connected and are separate components before being brought together to form the elongated hollow member 20".

[0057] In the embodiment of Figs. 9 and 10, the test strip receiving part 21" includes a planar surface 21A, which is spaced from a test strip receiving channel 26". The test strip covering part 22" includes a mating planar surface 22A, which is formed in a shape and size complementary to the planar surface 21A. When the test strip covering part 22" is brought into overlying relation to the test strip receiving part 21", the planar surfaces 21A,22A mate together. The surfaces can then be sealingly joined together by an appropriate method of connection, such as sealing by ultrasonic welding, rf (radio frequency) welding, plasma welding, adhesive or the like.

[0058] The overall design of the test strip holder, including the vent, measures and permits only a specific volume of liquid to be presented to the test strip. The volume is a final volume of liquid in the test strip itself after the pads and membrane are saturated. This volume can be adjusted by changing the wicking capacity of the test strip components.

Claims

1. A test strip holding apparatus, comprising:

   an elongated hollow member having an open end and a closed end;

   a support configured to hold a test strip within the elongated hollow member in a position spaced from inner walls of the elongated hollow member; and

one or more vents positioned between the open end and the closed end,

characterized in that said one or more vents are positioned at the same distance from said open end to vent the elongated hollow member at a distance from the closed end and to limit, by air pressure in the closed end, which is air tight sealed, the maximum height that a liquid can travel through said elongated hollow member from said open end toward said close end other than by capillary force along a test strip held on said support when said opened is dipped into said liquid.

2. The apparatus according to claim 1, characterized in that said one or more vents comprise a plurality of vents.

3. An apparatus according to claim 1, characterized in that the elongated hollow member has a circular cross-section.

4. An apparatus according to claim 1, characterized in that the closed end is formed by walls of the elongated hollow member.

5. An apparatus according to claim 1, characterized in that the closed end is closed by a sealing plug.

6. An apparatus according to claim 1, characterized in that the open end includes a plug having a through passage inserted into the open end of the elongated hollow member.

7. An apparatus according to claim 6, characterized in that the plug defines at least a portion of the support.

8. An apparatus according to claim 6, characterized in that the through passage has a diameter substantially equivalent to the width of the test strip to frictionally support the test strip within the through passage of the plug, spaced from inner walls of the elongated hollow member.

9. An apparatus according to claim 1, further including a test strip held by the support.

10. An apparatus according to claim 1, characterized in that the elongated hollow member includes a test strip receiving part and a test strip covering part, wherein the test strip receiving part is connectable to the test strip covering part.

11. An apparatus according to claim 10, characterized in that the elongated hollow member includes a test strip receiving part, including a flat surface and a test strip covering part including another flat surface complementary with the flat surface, wherein the flat surface and the another flat surface are sealed together.

12. An apparatus according to claim 10, characterized in that one of the test strip covering part and the test strip receiving part includes a groove and the other of the test strip covering part and the test strip receiving part includes aprojection, the projection being configured to sealingly fit into the groove, wherein the groove and projection fit together to define the elongated hollow member.

13. An apparatus according to claim 10, characterized in that the test strip receiving part includes a test strip channel configured to receive the test strip, the support being located within the test strip channel.

14. An apparatus according to claim 13, further including a stop proximate the open end capable of maintaining the test strip within the test strip channel.

15. An apparatus according to claim 13, characterized in that the channel comprises a center planar support surface surrounded by raised side portions that constrain movement of a test strip.

16. An apparatus according to claim 10, characterized in that said one or more vents are formed in the test strip covering part.

17. A method of testing a liquid using a test strip within a test strip holder, the method comprising the steps of: ,

supporting a test strip within an elongated hollow member having an open end, a closed end and a sidewall with one or more vents in the sidewall between the open end and the closed end, the test strip being spaced from inner walls of the elongated hollow member;
immersing the elongated hollow member into a liquid to be tested to at least a depth of the one or more vents, characterized in that said one or more vents are positioned at the same distance from said open end to vent the elongated hollow member at a distance from the closed end and to limit, by air pressure in the closed end, which is air tight sealed, the maximum height that said liquid travels through said elongated hollow member from said open end toward said closed end other than by capillary force along said test strip when said open end is dipped into said liquid up to and covering said one or more vents, thereby allowing the liquid to enter said hollow member only up to the level of said vent; and
observing an effect of the liquid on the test strip above said one or more vents .

18. The method according to claim 17, characterized in that the step of supporting the test strip includes frictionally supporting the test strip at a portion of the elongated hollow member where liquid enters.

19. The method according to claim 17, characterized in that the step of supporting the test strip includes supporting the test strip at a plurality of locations.

20. The method according to claim 17, characterized in that liquid travels up the test strip only by capillary action within the test strip.

Patentansprüche

1. Teststreifen-Haltevorrichtung mit:

einem länglichen hohlen Bauteil mit einem offenen Ende und einem geschlossenen Ende;
einer Stütze, die so ausgebildet ist, dass sie einen Teststreifen in dem länglichen hohlen Bauteil in einer Position hält, die von den Innenwänden des länglichen hohlen Bauteiles beabstandet ist; und
einem oder mehreren Entlüftungslöchern, die zwischen dem offenen Ende und dem geschlossenen Ende angeordnet sind,

dadurch gekennzeichnet, dass das eine oder die mehreren Entlüftungslöcher im gleichen Abstand von dem offenen Ende angeordnet sind, um das längliche hohle Bauteil in einem Abstand von dem geschlossenen Ende zu entlüften und durch einen Luftdruck in dem geschlossenen Ende, welches luftdicht versiegelt ist, die maximale Höhe zu beschränken, bis zu welcher eine Flüssigkeit von dem offenen Ende durch das längliche hohle Bauteil zum geschlossenen Ende wandern kann, und zwar anders als durch die Kapillarkraft, entlang eines Teststreifens, der auf der Stütze gehalten wird, wenn das offene Ende in die Flüssigkeit eingetaucht wird.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass das eine oder die mehreren Entlüftungslöcher eine Vielzahl von Entlüftungen aufweisen.

3. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass das längliche hohle Bauteil einen kreisförmigen Querschnitt hat.

4. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass das geschlossene Ende durch Wände des länglichen hohlen Bauteils ausgebildet wird.

5. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass das geschlossene Ende durch einen Abdichtstopfen geschlossen ist.

6. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass das offene Ende einen Stopfen umfasst, der einen Durchgangskanal hat, welcher in das offene Ende des länglichen hohlen Bauteils eingebracht ist.

7. Vorrichtung nach Anspruch 6, dadurch gekennzeichnet, dass der Stopfen mindestens einen Abschnitt der Stütze definiert.

8. Vorrichtung nach Anspruch 6, dadurch gekennzeichnet, dass der Durchgangskanal einen Durchmesser aufweist, der im Wesentlichen äquivalent zur Breite des Teststreifens ist, um den Teststreifen in dem Durchgangskanal des Stopfens durch Reibung zu stützen, und zwar im Abstand von den Innenwänden des länglichen hohlen Bauteils.

9. Vorrichtung nach Anspruch 2, die ferner die einen Teststreifen umfasst, der durch die Stütze gehalten wird.

10. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass das längliche hohle Bauteil ein Teststreifen-Aufnahmeteil und ein Teststreifen-Abdeckteil umfasst, wobei das Teststreifen-Aufnahmeteil mit dem Teststreifen-Abdeckteil verbindbar ist.

11. Vorrichtung nach Anspruch 10, dadurch gekennzeichnet, dass das längliche hohle Bauteil ein Teststreifen-Aufnahmeteil umfasst, welches eine flache Oberfläche hat, und ein Teststreifen-Abdeckteil, welches eine weitere flache Oberfläche hat, die zur flachen Oberfläche komplementär ist, wobei die flache Oberfläche und die weitere flache Oberfläche miteinander versiegelt sind.

12. Vorrichtung nach Anspruch 10, dadurch gekennzeichnet, dass entweder das Teststreifen-Abdeckteil oder das Teststreifen-Aufnahmeteil eine Rille umfasst und das Andere davon, das Teststreifen-Abdeckteil oder das Teststreifen-Aufnahmeteil, einen Vorsprung umfasst, wobei der Vorsprung so ausgebildet ist, dass er abdichtend in die Rille hinein passt, wobei die Rille und der Vorsprung zusammenpassen, um das längliche hohle Bauteil zu definieren.

13. Vorrichtung nach Anspruch 10, dadurch gekennzeichnet, dass das Teststreifen-Aufnahmeteil einen Teststreifenkanal umfasst, der so ausgebildet ist, dass er den Teststreifen aufnimmt, wobei die Stütze in dem Teststreifenkanal angeordnet ist.

14. Vorrichtung nach Anspruch 13, die ferner in der Nähe des offenen Endes eine Stoppereinrichtung um-

fasst, die dazu in der Lage ist, den Teststreifen in dem Teststreifenkanal zu halten.

15. Vorrichtung nach Anspruch 13, dadurch gekennzeichnet, dass der Kanal eine mittige planare Stützoberfläche umfasst, die durch erhabene Seitenabschnitte umgeben ist, welche die Bewegung des Teststreifens einschränken.

16. Vorrichtung nach Anspruch 10, dadurch gekennzeichnet, dass das eine oder die mehreren Entlüftungslöcher in dem Teststreifen-Abdeckteil ausgebildet sind.

17. Verfahren zum Testen einer Flüssigkeit und Verwendung eines Teststreifens in einem Teststreifenhalter, wobei das Verfahren die folgenden Schritte aufweist:

Stützen eines Teststreifens in einem länglichen hohlen Bauteil mit einem offenen Ende, einem geschlossenen Ende und einer Seitenwand mit einem oder mehreren Entlüftungslöchern in der Seitenwand zwischen dem offenen Ende und dem geschlossenen Ende, wobei der Teststreifen von den Innenwänden des länglichen hohlen Bauteils beabstandet ist;
Eintauchen des länglichen hohlen Bauteils in eine Flüssigkeit, die getestet werden soll, bis mindestens zu einer Tiefe des einen oder der mehreren Entlüftungslöcher, dadurch gekennzeichnet, dass eines oder mehrere Entlüftungslöcher im gleichen Abstand von dem offenen Ende angeordnet sind, um das längliche hohle Bauteil in einem Abstand von dem geschlossenen Ende, welches luftdicht versiegelt ist zu entlüften, die maximale Höhe, über die Flüssigkeit durch das längliche hohle Bauteil vom offenen Ende zum geschlossenen Ende hin anders als durch Kapillarkraft entlang des Teststreifens wandert, zu begrenzen, wenn das offene Ende in die Flüssigkeit eingetaucht wird, und zwar bis hin zu dem einen oder den mehreren Entlüftungslöchern, wobei diese abgedeckt werden, wodurch es der Flüssigkeit gestattet wird, in das hohle Bauteil nur bis zur Höhe der Entlüftung einzudringen; und
Beobachten des Effektes der Flüssigkeit auf dem Teststreifen oberhalb des einen oder der mehreren Entlüftungslöcher.

18. Verfahren nach Anspruch 17, dadurch gekennzeichnet, dass der Schritt des Stützens des Teststreifens das Stützen des Teststreifens durch Reibung an einem Abschnitt des länglichen hohlen Bauteils umfasst, wo Flüssigkeit eindringt.

19. Verfahren nach Anspruch 17, dadurch gekennzeichnet, dass der Schritt des Stützens des Teststreifens das Stützen des Teststreifens an mehreren Stellen umfasst.

20. Verfahren nach Anspruch 17, dadurch gekennzeichnet, dass die Flüssigkeit an dem Teststreifen nur durch Kapillarwirkung in den Teststreifen hinaufläuft.

Revendications

1. Dispositif porte-bandelette réactive, comprenant :

un élément allongé creux ayant une extrémité ouverte et une extrémité fermée ;
un support agencé pour tenir une bandelette réactive à l'intérieur de l'élément allongé creux et à distance des parois internes de l'élément allongé creux ; et
un ou plusieurs orifices situés entre l'extrémité ouverte et l'extrémité fermés,

caractérisé en ce que le ou lesdits orifices sont situés à la même distance de ladite extrémité ouverte pour évacuer l'air présent dans l'élément allongé creux à une certaine distance de l'extrémité fermée et pour limiter, par la pression de l'air à l'extrémité fermée qui ne laisse pas passer l'air, la hauteur maximale possible d'élévation d'un liquide dans ledit élément allongé creux depuis ladite extrémité ouverte vers ladite extrémité fermée autrement que par capillarité le long d'une bandelette réactive tenue sur ledit support lorsqu'on plonge ladite extrémité ouverte dans ledit liquide.

2. Dispositif selon la revendication 1, caractérisé en ce que le ou lesdits orifices comprennent d'une pluralité d'orifices.

3. Dispositif selon la revendication 1, caractérisé en ce que l'élément allongé creux a une section transversale circulaire.

4. Dispositif selon la revendication 1, caractérisé en ce que l'extrémité fermée est formée par des parois de l'élément allongé creux.

5. Dispositif selon la revendication 1, caractérisé en ce que l'extrémité fermée est fermée par un bouchon d'obturation.

6. Dispositif selon la revendication 1, caractérisé en ce que l'extrémité ouverte comporte un bouchon à passage traversant inséré dans l'extrémité ouverte de l'élément allongé creux.

7. Dispositif selon la revendication 6, caractérisé en

ce que le bouchon définit au moins une partie du support.

8. Dispositif selon la revendication 6, caractérisé en ce que le passage traversant a un diamètre sensiblement équivalent à la largeur de la bandelette réactive pour supporter à frottement la bandelette réactive dans le passage traversant du bouchon, à distance des parois internes de l'élément allongé creux.

9. Dispositif selon la revendication 1, comprenant en outre une bandelette réactive tenue par le support.

10. Dispositif selon la revendication 1, caractérisé en ce que l'élément allongé creux comporte une partie recevant une bandelette réactive et une partie couvrant une bandelette réactive, la partie recevant une bandelette réactive pouvant être reliée à la partie couvrant une bandelette réactive.

11. Dispositif selon la revendication 10, caractérisé en ce que l'élément allongé creux comporte une partie recevant une bandelette réactive, possédant une surface plane, et une partie couvrant une bandelette réactive, possédant une autre surface plane complémentaire de la surface plane, la surface plane et l'autre surface plane étant scellées l'une à l'autre.

12. Dispositif selon la revendication 10, caractérisé en ce que l'une parmi la partie couvrant une bandelette réactive et la partie recevant une bandelette réactive comporte une gorge et l'autre parmi la partie couvrant une bandelette réactive et la partie recevant une bandelette réactive comporte une saillie, la saillie étant agencée pour se loger dans la gorge en obturant celle-ci, la gorge et la saillie s'ajustant l'une avec l'autre pour définir l'élément allongé creux.

13. Dispositif selon la revendication 10, caractérisé en ce que la partie recevant une bande réactive comporte une rainure pour bandelette réactive, agencée pour recevoir la bandelette réactive, le support se trouvant dans la rainure pour bandelette réactive.

14. Dispositif selon la revendication 13, comprenant en outre une butée située très près de l'extrémité ouverte, permettant de maintenir la bandelette réactive dans la rainure pour bandelette réactive.

15. Dispositif selon la revendication 13, caractérisé en ce que la rainure comporte une surface plane centrale de support entourée par des parties latérales en relief qui empêchent la bandelette réactive de bouger.

16. Dispositif selon la revendication 10, caractérisé en ce que le ou lesdits orifices sont formés dans la partie couvrant une bandelette réactive.

17. Procédé pour analyser un liquide à l'aide d'une bandelette réactive placée dans un porte-bandelette réactive, le procédé comprenant les étapes consistant à :

supporter une bandelette réactive dans un élément allongé creux ayant une extrémité ouverte, une extrémité fermée et une paroi latérale avec un ou plusieurs orifices dans la paroi latérale entre l'extrémité ouverte et l'extrémité fermée, la bandelette réactive étant à distance des parois internes de l'élément allongé creux ; plonger l'élément allongé creux dans un liquide à analyser au moins jusqu'à la profondeur du ou desdits orifices,

caractérisé en ce que le ou lesdits orifices sont situés à la même distance de ladite extrémité ouverte pour évacuer l'air présent dans l'élément allongé creux à une certaine distance de l'extrémité fermée et pour limiter, par la pression de l'air à l'extrémité fermée qui ne laisse pas passer l'air, la hauteur maximale possible d'élévation d'un liquide dans ledit élément allongé creux depuis ladite extrémité ouverte vers ladite extrémité fermée autrement que par capillarité le long de ladite bandelette réactive lorsqu'on plonge ladite extrémité ouverte dans ledit liquide jusqu'à et en couvrant le ou lesdits orifices, en ne laissant ainsi le liquide pénétrer dans ledit élément creux que jusqu'au niveau dudit orifice ; et

observer un effet du liquide sur la bandelette réactive au-dessus du ou desdits orifices.

18. Procédé selon la revendication 17, caractérisé en ce que l'étape consistant à supporter la bandelette réactive consiste à supporter à frottement la bandelette réactive dans une partie de l'élément allongé creux où pénètre le liquide.

19. Procédé selon la revendication 17, caractérisé en ce que l'étape consistant à supporter la bandelette réactive consiste à supporter la bandelette réactive en plusieurs endroits.

20. Procédé selon la revendication 17, caractérisé en ce que le liquide ne s'élève dans la bandelette réactive que par capillarité dans la bandelette réactive.

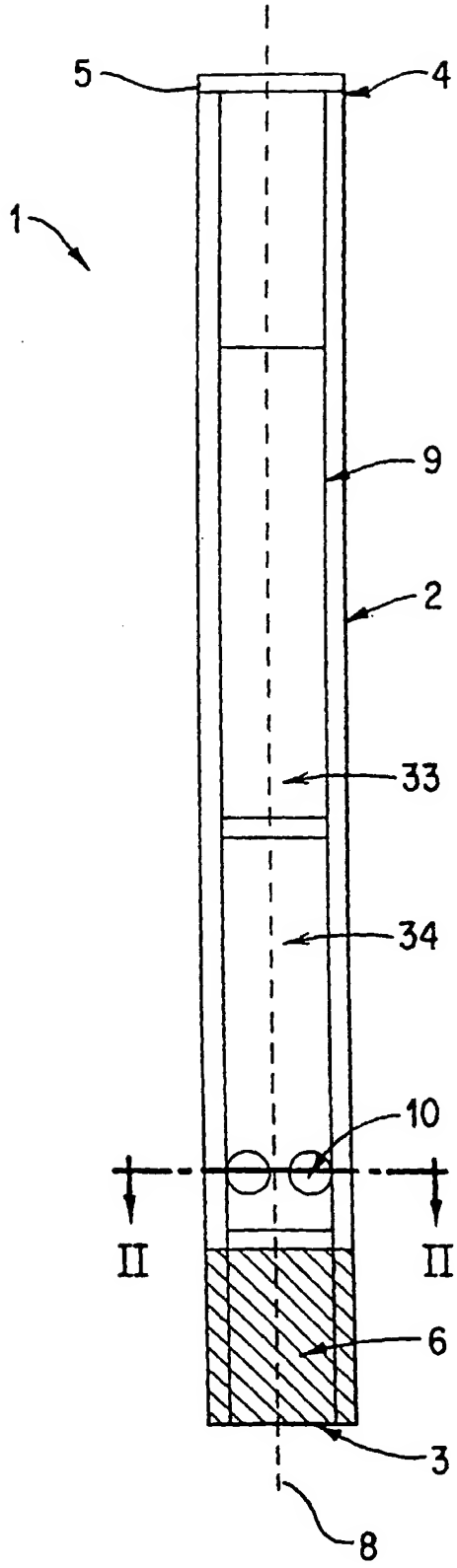

FIG. 1

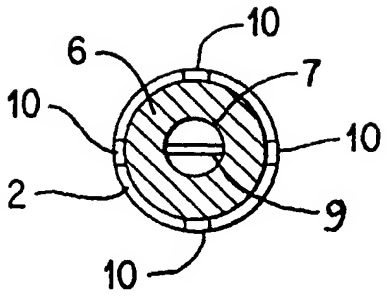

FIG. 2

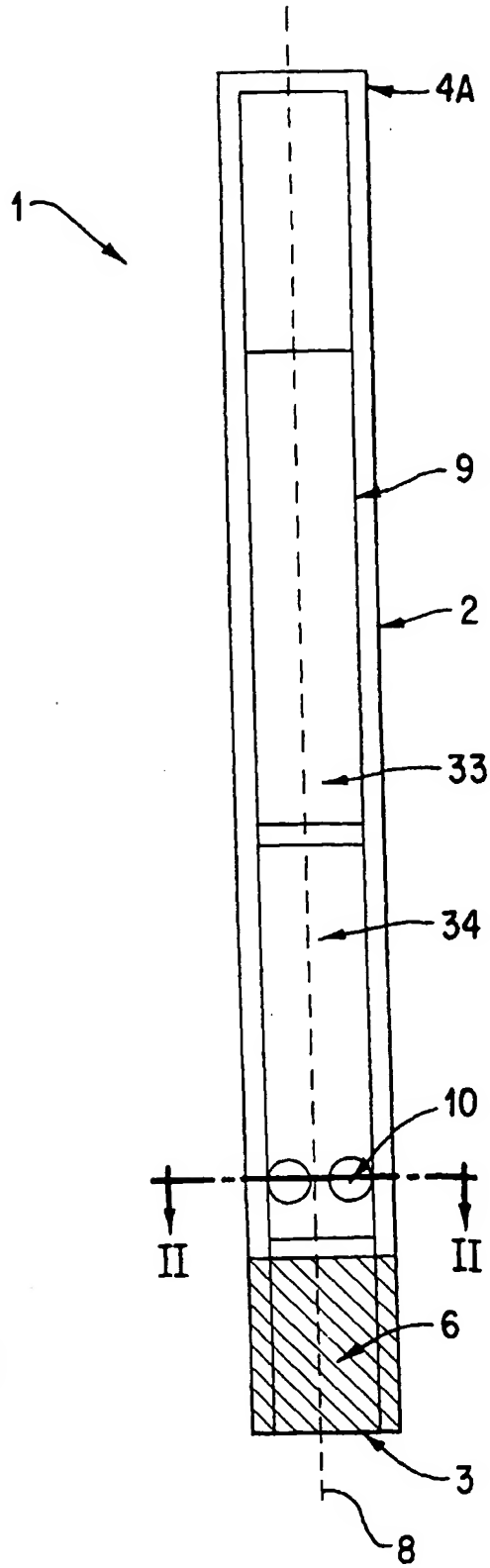

FIG. 1A

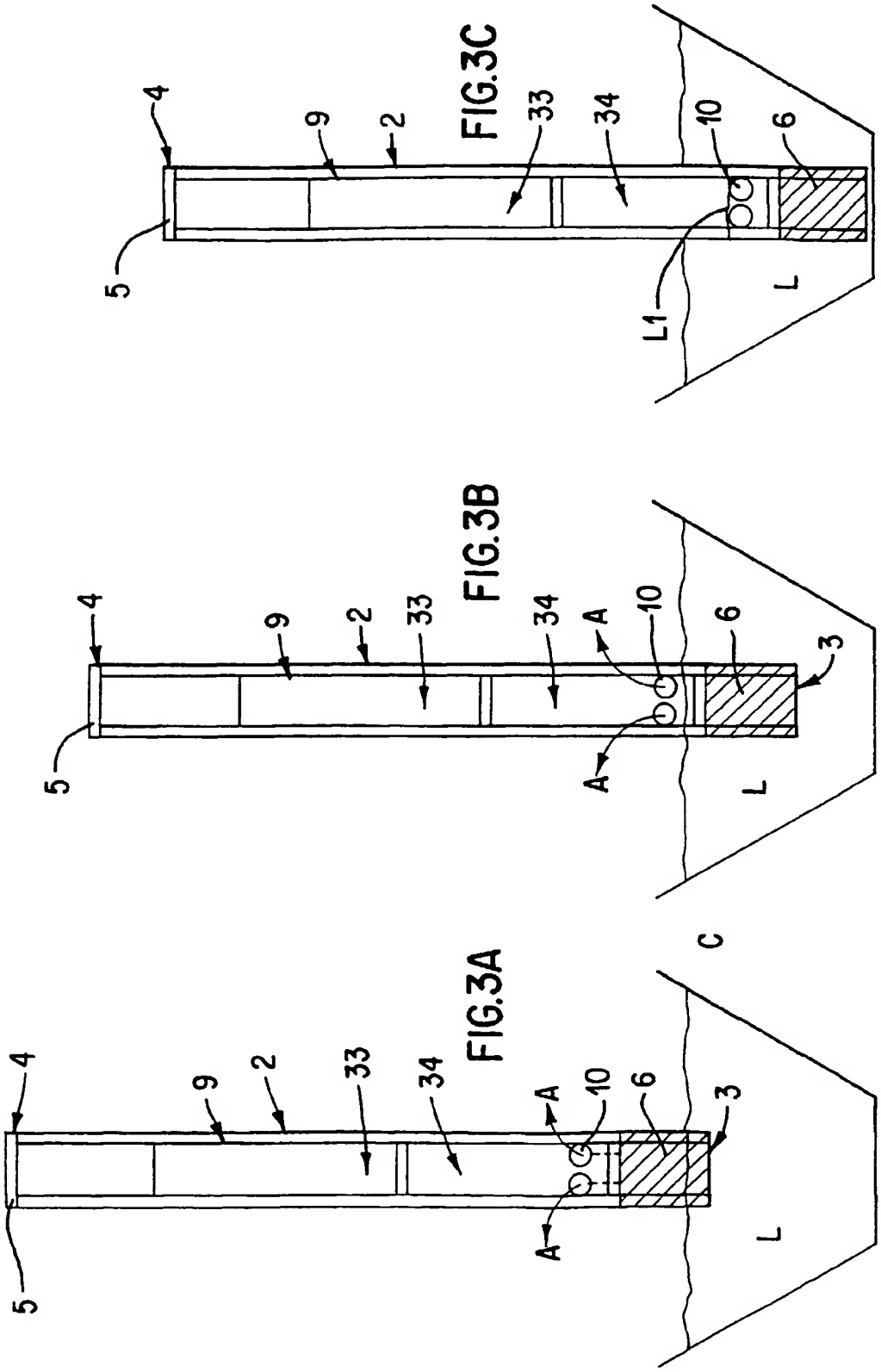
FIG.3C
4
9
2
33
34
10
6
5
L1
L
FIG.3B
4
9
2
33
34
A
10
6
3
5
A
L
FIG.3A
C
4
9
2
33
34
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3
5
A
L

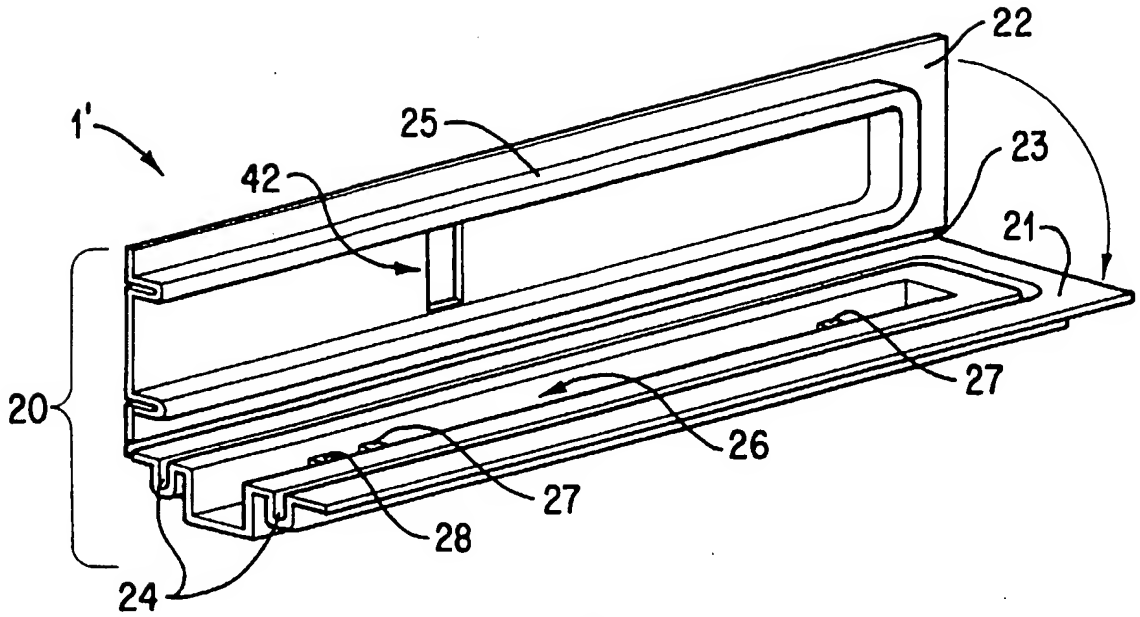
22
1'
25
42
23
21
20
27
26
27
28
24

FIG. 4

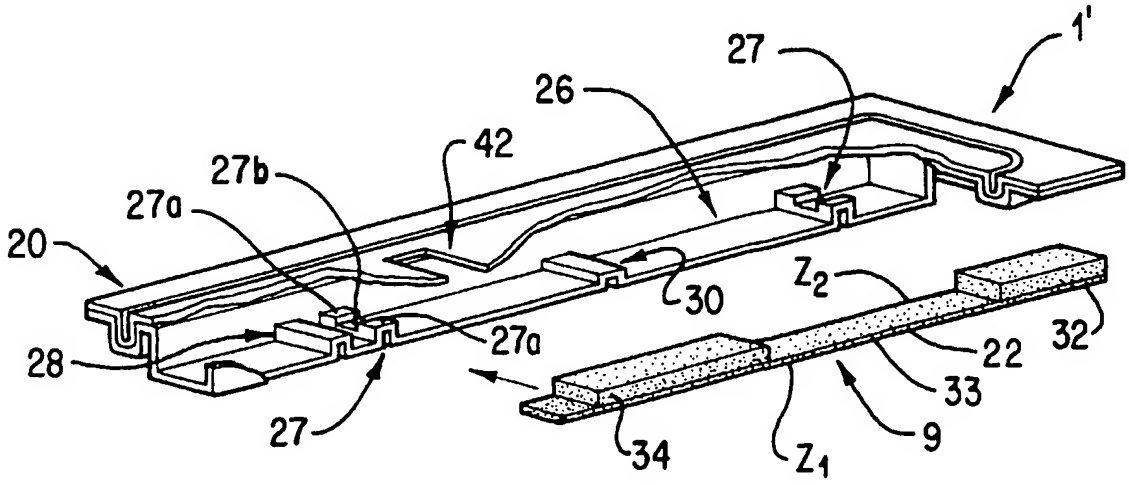
1'
27
26
42
27b
27a
20
30
Z_2
28
27a
22
32
33
27
34
Z_1
9

FIG. 5

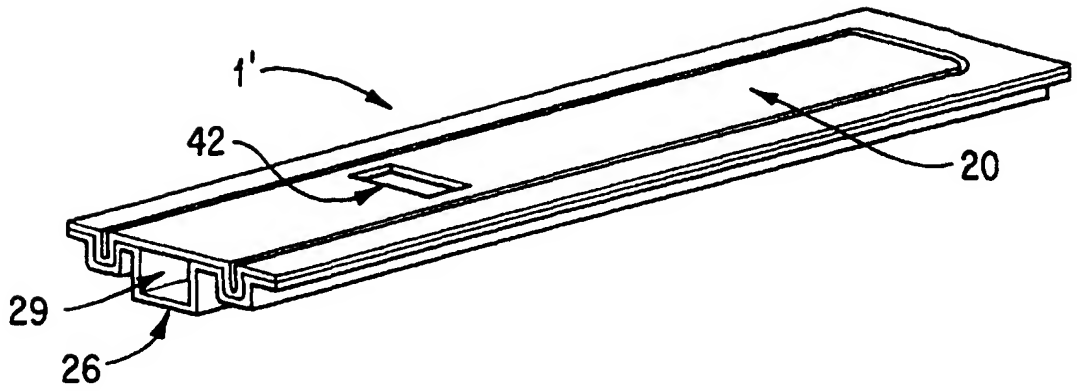

FIG. 6

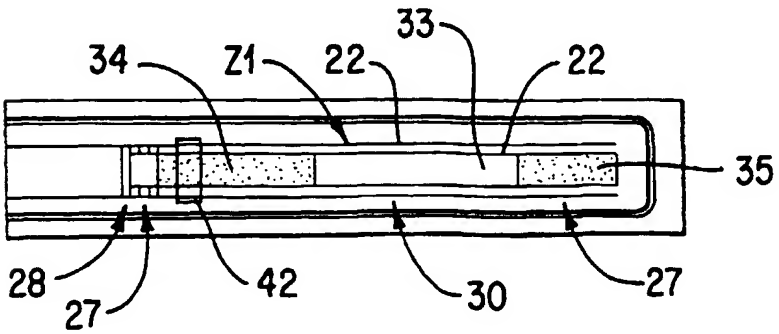

FIG. 7

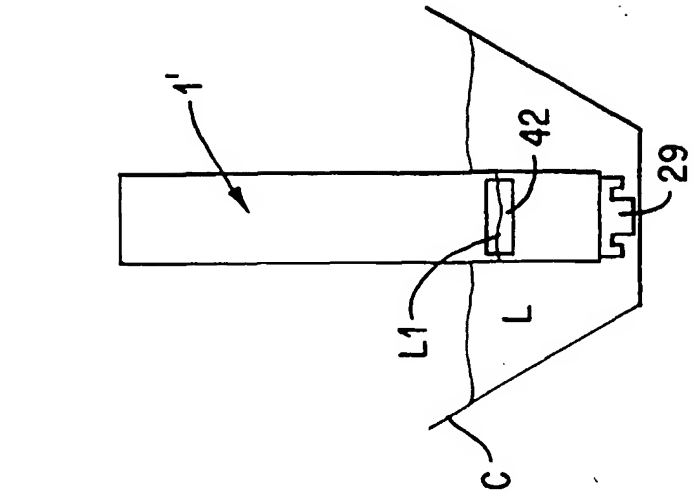

FIG.8C

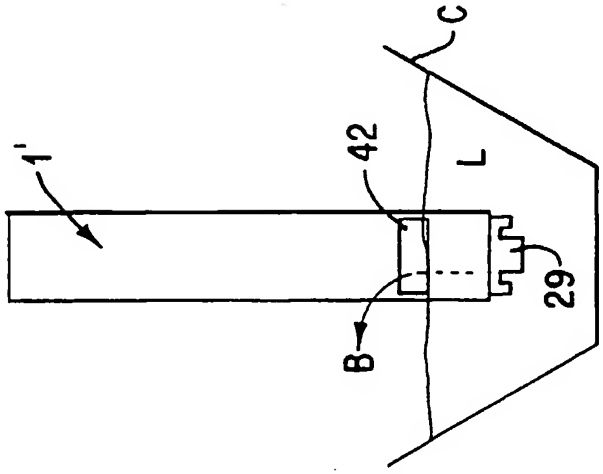

FIG.8B

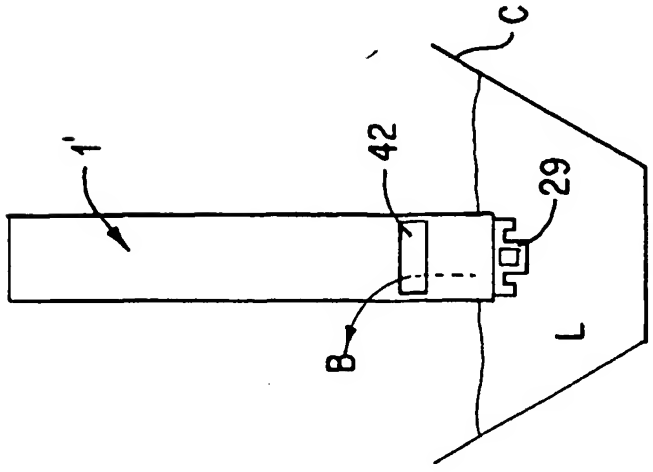

FIG.8A

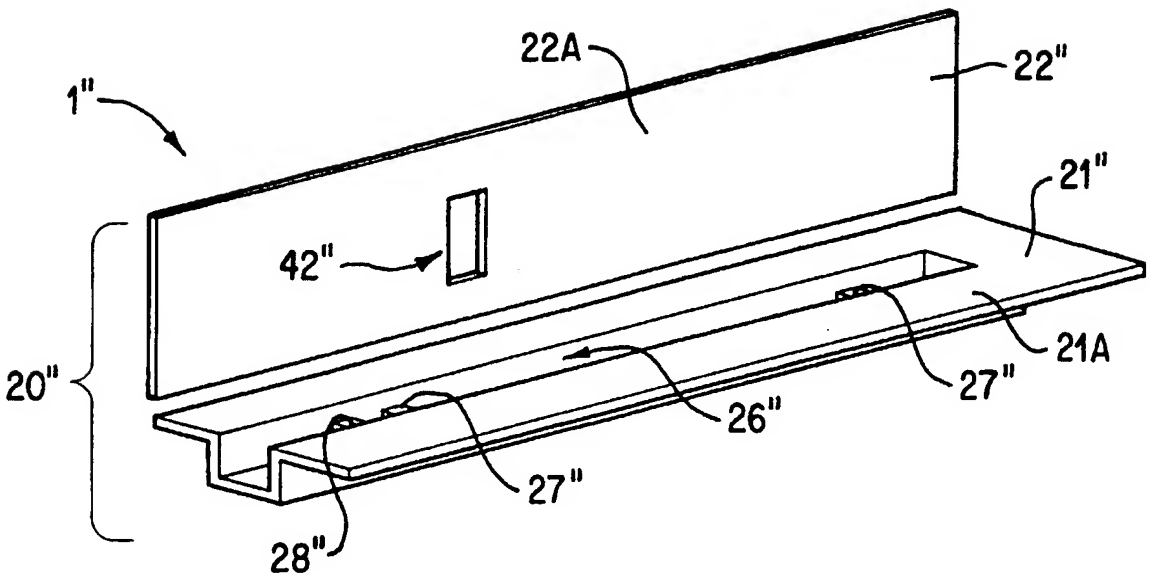

FIG. 9

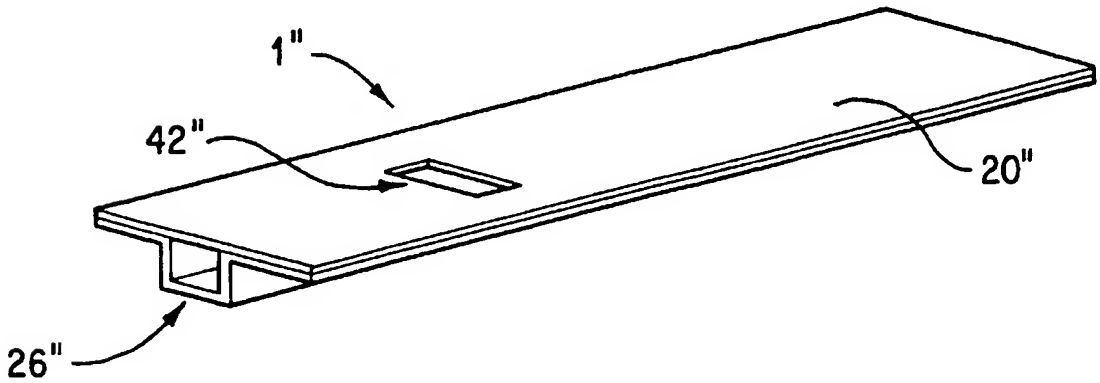

FIG. 10